UNITED STATES PATENT AND TRADEMARK OFFICE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>*1-21*</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>*1-21*</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>*20 September 2005*</u> is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date <u>*9/25/06*</u>.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Drawings

1.   The drawings are objected to because

-- Figs.1-5 include handwriting.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to

the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet,

even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure

must be removed from the replacement sheet, and where necessary, the remaining figures must

be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The

objection to the drawings will not be held in abeyance.

Specification

2.   The incorporation of essential material in the specification by reference to an

unpublished U.S. application, foreign application or patent, or to a publication is improper.

Applicant is required to amend the disclosure to include the material incorporated by reference,

if the material is relied upon to overcome any objection, rejection, or other requirement imposed

by the Office. The amendment must be accompanied by a statement executed by the applicant,

or a practitioner representing the applicant, stating that the material being inserted is the material

previously incorporated by reference and that the amendment contains no new matter. 37 CFR

1.57(f).

The attempt to incorporate subject matter into this application by reference to Nowinski

in paragraph 0002 is ineffective because it is a publication.

The attempt to incorporate subject matter into this application by reference to

WO02/069827 in paragraph 0035 is ineffective because it is a foreign application or patent.

The attempt to incorporate subject matter into this application by reference to

WO02/43003 in paragraph 0036 is ineffective because it is a foreign application or patent.

The attempt to incorporate subject matter into this application by reference to Hu et al in

paragraph 0045 is ineffective because it is a foreign application or patent.

3.   The abstract should be in narrative form and generally limited to a single

paragraph within the range of 50 to 150 words. The abstract should not exceed 25 lines of text.

The abstract exceeds 150 words and has three parts.

Claim Rejections - 35 USC § 101

4.   Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is

directed to non-statutory subject matter.

Claims 1-20 are rejected under 35 U.S.C. 101 as not falling within one of the four

statutory categories of invention. The Federal Circuit[1], relying upon Supreme Court precedent[2],

has indicated that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a particular

machine or apparatus, or (2) transform a particular article to a different state or thing. This is

referred to as the "machine or transformation test", whereby the recitation of a particular

machine or transformation of an article must impose meaningful limits on the claim's scope to

impart patent-eligibility (See Benson, 409 U.S. at 71-72), and the involvement of the machine or

transformation in the claimed process must not merely be insignificant extra-solution activity

(See Flook, 437 U.S. at 590"). While the instant claim(s) recite a series of steps or acts to be

performed, the claim(s) neither transform an article nor are positively tied to a particular machine

that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

(1. In re Bilski, 88 USPQ2d 1385 (Fed. Cir. 2008). 2. Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook,

437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780, 787-

88 (1876).)

Claims 1-20 do not require absolutely a machine to perform any recited steps. They fail

the machine test. Furthermore, the claims as recited do not provide external depiction of the

transformed data. They also fail the transformation test. Therefore, they are directed to non-

statutory subject matter in light of Bilski.

Claim Rejections - 35 USC § 112

5.   Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for the following reasons.

a.   Each of Claims 1 and 21 recites the limitation "(d) identifying object voxels from

the background voxels due to the partial volume effect and/or morphological erosion/opening".

The exact scope is not clear because the use of "and/or" and "erosion/opening".

b.   There are insufficient antecedent bases for the following limitations.

-- Claim 1 recites "the object voxel" in line 12.

c.   Claim 21 recites "the object voxels" in the last line. However, there are "a set of

object voxels from the foreground voxels" and "object voxels from the background voxels"

related to object voxels. Which one does it refer to? Or does it refer to the combination of them?

Claim Rejections - 35 USC § 102

6.   Claims 1-7, 9, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by

Brummer et al ("Automatic Detection of Brain Contours in MRI Data Sets," Marijn E. Brummer,

et al., IEEE TRANSACTIONS ON MEDICAL IMAGING. VOL 12 NO. 2 JUNE 1993, pages

153-166, listed in IDS).

Brummer teaches the following claims as explained with the cited portions.

1. A computer-based method for locating one or more landmarks using an MR image of

a brain, the method including the following automatic steps:

-- (a) identifying a region of interest (ROI) with a plane of the MR image, the plane

containing the landmark(s); (paragraphs 1 and 3 in section "II MRI Data"; A region including a

brain is a ROI. The contours of the brain are the landmarks. Fig. 6 shows one slice, a plane,

containing the landmarks.)

-- (b) binarising the plane of the MR image into foreground and background voxels based

on at least one threshold selected using anatomical knowledge; (paragraphs 3-5 in section "III

Description of the Technique"; paragraph 1 and last paragraph in section IV C "Brain Threshold

Determination"; paragraph 1 in section "V Morphological Operations"; The brain is the

foreground. Their surrounding structures are background. The data are binarized into masks.)

-- (c) identifying a set of object voxels from the foreground voxels, the set of object

voxels excluding voxels which were only classified as foreground voxels due to proximity of

cortical and non-cortical structures; (paragraph 2 in section "II MRI Data"; the brain and the

ventricles, (paragraph 1 in section "V Morphological Operations"; paragraph 1 in page 161 and

Fig. 14; The voxels far away from the brain, namely close to the skin, are removed.)

-- (d) identifying object voxels from the background voxels due to the partial volume

effect and/or morphological erosion/opening; (paragraph 1 in section "II MRI Data"; section "V

Morphological Operations"; Partial volume effects are used.)

-- (e) identifying the one or more landmarks using the object voxel. (paragraphs 1 and 2

in section "VI Mask Image Overlap Test Algorithm"; The labeled objects are the identified

landmarks. Fig. 17 shows one example of landmarks. Contours, which are landmarks, of brains

are identified as shown in Fig. 18.)

2. A method according to claim 1 in which the step of identifying the object voxels is

performed in two stages:

(i) morphological processing which excludes foreground voxels which may not be object voxels, (erosion in section "V Morphological Operations" as shown in Fig. 10(b))

(ii) restoring voxels which have been incorrectly excluded in the morphological processing. (label image dilation in section "V Morphological Operations" as shown in Fig. 10(d))

3. A method according to claim 2 in which the step of identifying the object voxels further includes applying anatomical knowledge to identify the object voxels. (paragraph 1 in section "V Morphological Operations")

4. A method according to claim 3 in which the anatomical knowledge is knowledge about the expected shapes of cortical and/or non-cortical structures. (paragraph 1 in section "V Morphological Operations")

5. A method according to claim 1, wherein the threshold is selected by the steps of:

(i) using prior knowledge about the image to derive an intensity range of voxels said region of interest; (Fig. 5 and section IV B "Background Threshold Determination"; The prior knowledge about the image is that its noise part shall fit Rayleight function.)

(ii) obtaining a frequency distribution of intensities within the said intensity range of voxels within said region of interest; (Fig. 5 and section IV B "Background Threshold Determination"; eq. (14)) and

(iii) using the frequency distribution to derive an intensity threshold. (Fig. 5 and section IV B "Background Threshold Determination"; eq. (15))

6. A method according to claim 5 in which the intensity threshold is selected by minimizing a function which is a sum of variances of the intensities below and above the

threshold. (Fig. 5 and section IV B "Background Threshold Determination"; A threshold is derived with minimizing an error of eq. (15).)

7. A method according to claim 6 in which said function is a weighted sum defined based on two constants W_1 and W_2. (As shown in Equation (15), $W_1 = 1$ and $W_2 = 1$.)

9. A method according to claim 1, wherein the steps (a) to (e) are performed repeatedly, in each set of steps identifying at least one corresponding landmark. (Fig. 1 shows that they are slices each having at least contour as landmarks. The steps (a) to (e) are performed repeatedly for each slice.)

Claim 21 is a system corresponding to the method of Claim 1. Because Brummer also teaches a system to implement the method of Claim 1 (section "VII Results"; SUN 3PIXAR platform), Brummer also teaches Claim 21.

Claim Rejections - 35 USC § 103

7.   Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brummer as applied to Claim 1, and further in view of Nowinski et al ("A locus-driven mechanism for rapid and automated atlas assisted analysis of functional images by using the Brain Atlas for Functional Imaging," Wieslaw L. Nowinski, et al., Neurosurg Focus 15 (1): Article 3, July 15, 2003, pages 1-7 listed in IDS.)

Brummer teaches the parental Claim 1. Brummer further teaches:

-- for Claim 10, wherein in step (a) the region of interest being defined within the AP plane; (Figs. 1, 6 and 17; Fig. 6 explicitly shows the AP plane.)

-- for Claim 11,

- wherein step (c) comprises: performing at least one morphological opening operation on the binarized image obtained in step (b) (section "V Morphological Operations")

- classifying one or more voxels of the image(s) obtained by the opening operation(s) as object voxels or otherwise according to at least one criterion based on distances in the image(s) obtained by the opening operation(s) and anatomical knowledge; (paragraph 2 in section "II MRI Data"; the brain and the ventricles, (paragraph 1 in section "V Morphological Operations"; paragraph 1 in page 161 and Fig. 14; The voxels far away from the brain, namely close to the skin, are removed.)

-- for Claim 12, prior to classifying the voxels, a maximum distance maxDSkull is obtained from a distance transform of the ROI; (paragraph 1 of page 161, The maxDSkull is defined here as 1.5 times of that from skull to the skin.)

-- for Claim 13, wherein the classifying step comprises: restoring object voxels located far from the skull, which were lost due to the morphological opening operation(s); restoring object voxels around the boundaries lost due to the morphological opening operation(s); and restoring object voxels lost due to the partial volume effect; (Label image dilation in section "V Morphological Operations" as shown in Fig. 10(d) restores all of the above three cases.)

-- for Claim 15, wherein step (c) comprises:

- performing at least one morphological opening operation on the binarized image obtained in step (b); (section "V Morphological Operations")

- classifying as object voxels one or more voxels of the image(s) obtained by the morphological opening operation(s) if they belong to eight voxels immediately adjacent to an

object voxel and if their intensity value in the MR image is higher than a value defined in

relation to a second threshold; ("connectivity" section in page 158; "Labeling of Connected

components" and Dilation of Label Image" sections in page 159; Fig. 8; The labeling is done by

comparing MR image to a 1st and 2nd thresholds.)

      -- for Claim 18, in step (c), (i) at least one morphological opening operation, and/or (ii) at

least one seeding operation, are performed on the binarized image obtained in step (b); (section

"V Morphological Operations")

      -- for Claim 19, in step (c), one or more voxels of the image(s) obtained by the

morphological opening operation(s) which are not presently classified as object voxels are re-

classified as object voxels if they are one of the eight immediate neighbors of an object voxel

and if their intensity value in the MR image is higher than a value defined in relation to a second

threshold; ("connectivity" section in page 158; "Labeling of Connected components" and

Dilation of Label Image" sections in page 159; Fig. 8; The labeling is done by comparing MR

image to a 1st and 2nd thresholds.)

      -- for Claim 20, wherein the left and right halves of the brain are treated separately, the

selected half of the brain having been selected based on a predefined criterion. (the last

paragraph of the left column in page 157; The superior half of head, therefore the superior half of

the brain, is selected for processing. The left and right halves of the brain are treated separately.

Inherently, a predefined criterion is used to determine the superior half and the left and right

halves of the brain are treated separately.)

      However, Brummer does not teach features related to A, P, L, R, S, and I landmarks as

recited.

Nowinski teaches Talairach landmarks for brain in which:

-- for Claim 10, locate A, P, L and R landmarks are located, and that the most anterior

and most posterior of the object voxels being taken respectively as the vertical coordinates of the

A and P landmarks respectively, and the extreme horizontal components of the object voxels are

taken as the horizontal coordinates of the L and R landmarks respectively; (Figs. 2 and 3 and

Table 1, page 4)

-- for Claim 14,

- defining the region of interest within a virtual plane obtained from a VPC coronal slice;

(Figs. 2 and 3 and Table 1, page 4)

- identifying the position of the S landmark as the most superior point of the object

voxels; (Table 1)

-- for Claim 16, an I landmark is identified, comprising:

- defining the region of interest within a VAC plane; (Figs. 2 and 3 and Table 1, page 4)

- defining the I landmark as the most inferior point of the object voxels. (Figs. 2 and 3

and Table 1, page 4)

It is desirable to map a brain 3D image into a user-friendly brain atlas based on Talairach

landmarks. It would have been obvious to one of ordinary skill in the art, at the time of the

invention, to locate A, P, L and R landmarks and identify S and I landmarks from Brummer's 3D

contour information of the whole brain based on Nowinski's teaching because the combination

makes the final brain map more user-friendly. The combination thus teaches:

-- wherein steps (a) to (d) are performed to locate A, P, L and R landmarks, and wherein

in step (a) the region of interest being defined within the AP plane; and in step (e) the most

anterior and most posterior of the object voxels being taken respectively as the vertical

coordinates of the A and P landmarks respectively, and the extreme horizontal components of the

object voxels are taken as the horizontal coordinates of the L and R landmarks respectively;

-- wherein steps (a) to (d) are performed to obtain an S landmark, the method comprising:

in step (a), defining the region of interest within a virtual plane obtained from a VPC coronal

slice; and in step (e), identifying the position of the S landmark as the most superior point of the

object voxels;

-- wherein the set of steps (a) to (d) is performed to identify an I landmark, comprising: in

step (a), defining the region of interest within a VAC plane; in step (e), defining the I landmark

as the most inferior point of the object voxels;

-- wherein the left and right halves of the brain are treated separately, and the object

voxels used to obtain the location of the I landmark relate to a selected half of the brain, the

selected half of the brain having been selected based on a predefined criterion.

Because the threshold is determined in the combination before determining an S

landmark, the combination also teaches "which the threshold is obtained during a preceding

process of locating an S landmark" recited in Claim 17.

Allowable Subject Matter

8.   Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35

U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations

of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter. The prior art fails to teach the method of Claim 8 which specifically comprises the following feature in combination with other recited limitations:

-- the specific equation for calculating the weighted sum recited in Claim 8.

Conclusion

9.   The prior art made of record in form PTO-892 and not relied upon is considered pertinent to applicant's disclosure.

10.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Wenpeng Chen whose telephone number is 571-272-7431. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on 571-272-7453. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 571-273-8300 for After Final communications. TC 2600's customer service number is 571-272-2600.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-2600.

/Wenpeng Chen/
Primary Examiner, Art Unit 2624

May 29, 2009